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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,698	09/08/2000	Samuel C Silverstein	60467/JPW/GJG	3655

7590

10/02/2002

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EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,698

Applicant(s)

SILVERSTEIN ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 78.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-32 are pending.

Election/Restrictions

Upon reconsideration, the prior art search was extended to include all species.

Specification

1. The abstract of the disclosure is objected to because It is not clear what the subject of the third sentence is. Clarification is required. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of delivering an antigen to a Class I MHC receptor to induce immunity against the antigen in a subject comprising filling particles with antigen and ATP, coating said particles with a ligand for an antigen presenting cell, incubating said particles with antigen presenting cells and either A) administering said antigen presenting cells to a subject, or B) further incubated said particles with lymphocytes isolated from the subject having the disease and administering said lymphocytes to the subject.

The instant specification discloses on pages 39-41 that prophetically mice will be administered red blood cell ghosts containing peptide and ATP, and that the formation of CTLs will be produced. Pages 40-41 discloses that said experiments will provide insight into the cellular mechanism by which apoptotic cells deliver antigenic peptides to Class I MHC of APC and may uncover a novel and potentially clinically useful protocol for activating CTLs. However, based on the limited disclosed prophetic examples, it would require undue experimentation to determine the effectiveness of the recited method encompassing any particle and any ligand and any cytokine and any antigen presenting cell, that would be effective in inducing immunity against any antigen relevant to any disease, without further guidance and direction from the instant specification.

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The instant specification discloses on pages 36-37 that IgG coated sheep red blood cell ghosts containing dye and ATP were phagocytosed by J774 macrophage cells in vitro and that the dye was present in the cytoplasm. However, it would require undue experimentation to determine if any antigen engulfed into the cytoplasm would be presented in a Class I restricted fashion, since Koppelman et al (IDS) teach that though proteolytic processing of peptides may occur in the cytoplasm, subsequent processing is completed in the ER; thus peptide transport into the ER may be selective and occurs before binding to the MHC Class I molecules antigen in the ER (see entire article, including first paragraph of column 1, page 3912).

Given the insufficient guidance and direction regarding the effectiveness of any of the recited administered cells in delivering an antigen to an Class I MHC receptor to induce immunity against the antigen in a subject, it would require undue experimentation for one of skill to determine specific method steps that would be effective in a subject having a disease. In view of the quantity of experimentation, the limited working examples, the unpredictability in the art and the lack of sufficient guidance in the specification, it would require undue experimentation to practice the claimed invention.

Conclusion

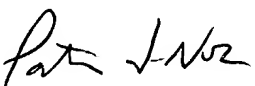
No Claim is allowed,

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner
September 25, 2002


Patrick J. Nolan, Ph.D.
Primary Patent Examiner,
Group 1640